

**Raymond M. Taniguchi, M.D., F.A.C.S.**  
**Incorporated**

**Neurological Surgery**  
1380 Lusitana Street, Suite 415 • Honolulu, Hawaii 96813  
Telephone: (808) 538-6520 • Fax: (808) 521-7523

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Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Gentlemen:

RE: Docket No. 97N-484S

I have been informed that there is an FDA proposal to regulate allograft tissue.

It is really a pity to hear that even allograft tissue will come under rigid FDA regulations. This will undoubtedly increase the cost of allografts even further to be almost prohibitive and to jack up the costs of medicine even further.

I can remember when Dr. Ralph Cloward and I would take the cadaver bones, prepare them and sterilize them with utmost care and charge \$50 for a bone graft. To my knowledge there has not been a single case of infection or passage of AIDS by our present methods of sterilization, the 20/20 expose notwithstanding. A single bone graft now costs the patient a \$1300 at our hospital mostly because of the enormous amount of paperwork involved. To think that yet another regulation is forthcoming is simply mind-boggling.

I am glad I am retiring in the year 2000.

Sincerely yours,

*Ray Taniguchi MD*

Raymond M. Taniguchi, M.D.

bgi

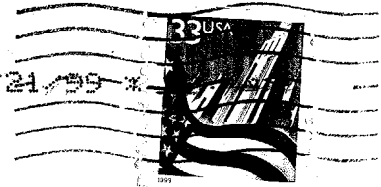
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Honolulu, Hawaii 96813

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